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BEFORE THE SELECT COMMITTEE ON HOMELAND SECURITY

REGARDING PROJECT BIOSHIELD ACT OF 2003

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TESTIMONY

Before the Select Committee on Homeland Security
Regarding Creating a Viable Defense Industry

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Mr. Chairman and members of the Committee, it is an honor for me to testify before you today regarding Project BioShield and how to jump-start the creation of a sustainable biodefense industry. Mr. Chairman, I applaud your immediate consideration of the steps necessary to incentivize the pharmaceutical and biotech industries to join as partners with the Department of Health and Human Services, the Department of Homeland Security and the Department of Defense to combat the evolving nature of agents of bioterrorism.

I appear before you today as a private attorney who has represented over thirty pharmaceuticals and biotechs in their contracting with the Department of Veterans Affairs, the Department of Defense, the Public Health Service, as well as directly representing companies in their individual bids to create a smallpox vaccine pre-9/11 from the CDC, a post-9/11 smallpox procurement by the Center for Disease Control and a recombinant protective antigen for anthrax issued by the National Institutes of Health.

Based on my view of how government agencies have operated in these procurements, as well as my intimate knowledge of what it will take to incentivize those to participate in a

biodefense industry, I offer, with supporting analysis, four ideas for your immediate consideration.

1. Agency procurement officials should create for each needed drug and diagnostic a Master Agreement between a successful bidder(s) and HHS which identifies clearly who will pay or share in the research development phase of the agreement, clarify there is a linkage between successful R&D and a guaranteed production contract within the same Master Agreement, set forth the allocation of intellectual property rights including a private company's unfettered right to commercialize the product for worldwide sales, and that the Master Agreement will recognize payments sufficient to amortize investment, which would include return on capital and return of capital, particularly in the event of early termination should the needs of the agency be directed elsewhere due to changes in bioterror threats.

2. The procurement vehicle identified above as the Master Agreement should allow a Secretary to depart from the very stiff and burdensome Federal Acquisition Regulations which govern contracts, grants and cooperative agreements, and instead embrace "Other Transactions" which provide for commercial-like terms and conditions which are more likely to attract private industry, yet can also provide for protection of the Federal Treasury.

3. Provide a clear statement that participating industry will be protected from product liability law suits by invocation of Public Law 85-804 or direct

statutory immunization. Since it appears that the Safety Act - which embraces the Government Contractor Defense – may be interpreted to apply on in the event of a terrorist attack – there should be a clarification that it, as well as Public Law 85-804, applies during the development and production phase of any counter measure under the Master Agreement.

4. Consider jump-starting the biodefense industry by seizing upon the express authority under the Defense Production Act ("DPA") of 1950, as amended to convene a meeting of all relevant companies competing for government contracts requesting the development and production of certain vaccines and counter measures for national defense purposes. Under such authority, the government may provide immunity from potential anti-trust liability to a company that participates in a process, the objective of which is to address issues of common concern to industry and the government. The government may, in exercising this authority, require a competitor to act in collaboration or share information that otherwise that could not be shared due to anti-trust laws and regulations.

I expand upon these four points below:

I. Provide for Express Authority to Enter into a Single Agreement for Research, Development and Production, A/K/A, The Master Agreement

We support strongly the need to provide for the possibility of the Federal Government entering into agreements (including contracts, grants, cooperative agreements, and "Other

Transactions,") that permit a biodefense contractor to engage in research and development with the assurance of production under a single agreement. While this appears to be the intention of the BioShield legislation, the proposed legislation does not make this authority crystal clear. It is essential there exists a certainty that satisfactory completion of research and development will lead to a manufacturing agreement.

It is also my experience in order to stimulate private investment and biodefense counter measure research, development and production, private investors must be assured that they have the potential to receive a return on their investment, both in the price of the end product and in the event the government elects to terminate the agreement for its convenience. The proposed BioShield legislation does not account for the implications of using private investment to finance research, development, and production of biomedical counter measures.

I suggest language be included in the proposed legislation that permits the Secretary of Health and Human Services to enter into agreements that allow the end price of any biomedical counter measure to reflect the cost of private financing, including cost of capital and return on equity.

In addition, under the current Federal Acquisition Regulations ("FAR") when a contract is terminated for the convenience of the government, contractors may recover the cost of performance through the date of termination plus a reasonable profit on those costs in addition to settlement expenses associated with ceasing performance, negotiating termination liability, and disposing of equipment and materials. The terms vary slightly depending upon the specific language of the "Termination for Convenience" Clause used in the contract.

However, one of the costs the FAR expressly prohibits – and one which very likely will apply to Project BioShield's contract – is capital financial cost.

Specifically, the program envisioned by the proposed BioShield legislation likely will be awarded via competitive negotiations. In such instances, the agency, here, HHS, negotiates proposals with one or more contractors. In such cases, the FAR expressly prohibits contractors from recovering as part of their contract price interest on borrowings (however represented) as well as cost of financing and refinance capital. See, FAR 31.205-20. Therefore, to recover return on equity costs and other capital financing arrangements, the existing regulations must be overridden.

In order to facilitate this change, I suggest language be included in the proposed legislation that requires the Secretary of Health and Human Services to include within an agreement a termination clause that requires costs of capital and return on equity to be included in any settlement in any event the government terminates the agreement for convenience.

Additionally, I propose that any Master Agreement[1] entered into between the government and the industry allocate clearly intellectual property rights. There is currently a problem, as discussed below, by reconciling the Bayh-Dole law with how the agencies have conducted their procurements for smallpox and anthrax.

[1] There is precedent for the term Master Agreement as by federal law pharmaceuticals which manufacture branded drugs enter into a Master Agreement with the Secretary of the VA to be eligible to participate in Medicaid and sales to the VA. 38 U.S.C. 8126.

In particular, the Bayh-Dole Act, in general, permits election by contractors to title of intellectual property made in performing federally funded R&D contracts. The government gets at a minimum a royalty free use called "government purpose license rights." The contractor's elections must include notification to the government of the invention, pursuant of the patent rights, or else the government has the right to march in and take over those rights or give them to a third-party. In a nutshell, the problem is that even in the event of a timely and successful election, the government's retention of government purpose license rights arguably allows the government to use these rights to meet "certain health and safety needs." It is unclear under this standard whether the intellectual property developed by one contract or could be given by the government to another for future R&D and production purposes in the event of a so-called health emergency.

An example of this confusion is found in both the recent smallpox and anthrax procurements. In the smallpox procurement for one hundred and fifty million doses, the successful bidder was to develop a new vaccine on a fixed-price per dose[2] It is unclear who will own the intellectual property rights for the newly developed vaccine.

Likewise, the anthrax procurement recently awarded by NIH was only for R&D (in two phases) and not production. Indeed, the solicitation issued April 22, 2002 provided that in the first phase (Phase One) (up to twelve months), the successful contractor was to develop a pilot lot and two thousand doses, as well as protocols for Phase One and Phase

[2] I note that fixed price development contracting has long been prohibited by Congress for DOD weapon system contracting and it appears the lesson has not been learned here.

Two clinical trials. The contractor was also to produce a plan to produce twenty-five million doses. The contractors were to be notified that on or before the twelve-month period, HHS would convene a blue ribbon panel to select one or more of the Phase One contractors to be permitted to complete with government money clinical studies over the next six months, i.e., Phase Two. This was then to be an overall eighteen month development contract finishing in March 2004, eighteen months from the award date of September 2002.

Most interestingly, the RFP also stated that the production contract – not related to the R&D contract – would be assembled and put out for a bid by May 2003. It is certainly unclear how any intellectual property being developed over the eighteen month period from the award date of September 2002 through March 2004 will be allocated between the R&D contractor and those bidders interested in a production contract under a solicitation issued May 2003.

Based on the foregoing, the various Secretary should have the authority to "link" R&D with production so that there is certainty through this process. I am not suggesting – as discussed below under "Other Transactions" – that the government be the sole financier of the R&D phase, but instead announce clearly that the development of a successful counter measure will vest the contractor a long-term production contract (absent a change in "threat" "when a termination for convenience is appropriate). Indeed, the actual price of the items to be manufactured can be determined at the end of the R&D phase by negotiation in accordance with established government contracts procedures and other guidance negotiated in the initial contract award.

II. OTHER TRANSACTIONS

The term "other transactions" comes from legislation at 10 U.S.C. 2371 where Congress authorized DOD to enter into to "transactions…other than contracts, cooperative agreements and grants" to fund research and development efforts. It also covers efforts to develop "prototype" weapon systems under more recent legislation, namely Section 845 of the 1994 DOD authorization Act. Other transactions are viewed as being enormously helpful in expanding the field of companies that are willing to perform government contracts, specifically those companies that are predominately commercial like pharmaceuticals and biotech companies which are otherwise not willing to sign-up to the government's requirements regarding intellectual property, cost accounting, pricing and other circumstances which they consider unacceptable to the conduct for their business.

Under 10 U.S.C. 2371, the Department of Defense will pay no more than fifty percent of the total R&D costs, and this guideline could be used to allocate the responsibility for R&D costs under the first phase of the Master Agreement. As stated previously, after the R&D phase, the government and industry can enter into a price determination for the cost of each production unit.

The added benefits of "other transactions" are that they depart from the very stiff federal acquisition regulations which afford the government with almost unfettered discretion to terminate contracts, audit costs, eliminate foreign places of production, gain strong IP rights, and provide no indemnification. Under other transactions, several of these authorities could be minimized yet still give the government over the procurement. In

particular, rather than terminating a contractor for default should it miss one deadline or determine the scope of the work is commercially impossible, the parties can agree to a termination at will that would allocate responsibility for costs incurred to date; also, the government can under other transactions minimize the amount of audit requiring review of contractors books and records; likewise, there could be a more clear allocation of intellectual property and patent rights than as provided under the Bayh-Dole Act now; and finally, Public Law 85-804 indemnification and coverage is clearly permitted under other transactions.

III. PROVIDE FOR THE AUTHORITY TO INDEMNIFY AND/OR LIMIT THE EXTENT OF LIABILITY FOR ANY CONTRACTOR ENGAGING IN RESEARCH, DEVELOPMENT AND PRODUCTION IN BIO-DEFENSE COUNTERMEASURES

The issue of the potential liability for any entity that provides, or performs research and development related to, biodefense countermeasures absolutely must be addressed in order to stimulate private sector interest in entering into agreements for such countermeasures. My experience was that the absence of liability protection was a major obstacle in the recent procurement for NIH for the development for the next generation anthrax vaccine, was a major obstacle in the pre-9/11 first CDC procurement for forty million doses of smallpox vaccine where the winning contractor was required to carry its own insurance, and continues to be a major hurdle today. Contractors will try to obtain commercial insurance, but the practical reality today is that it is unlikely to be available for

these projects given their nature. The proposed legislation is silent with respect to addressing liability.

Both the Secretary of Health and Human Services and the Secretary of Homeland Security currently have the authority to provide for federal indemnity to private entities engaging in research, development, and production of biomedical countermeasures under Public Law 85804. However, use of such authorities are extremely rare. It is important to note that President Bush recently revised Executive Order 10, 789 governing use of the authority to provide for indemnity under Public Law 85-804. These revisions add two additional levels of coordination and approval for all agencies other than DOD before indemnification may be given to a contractor. I am also concerned that the use of the government contractor defense under the Safety Act only applies in the event of a terrorist act, and could be read to not apply to the development of vaccines and counter measures after 9/11 or until there is another similar incident.

Finally, while HHS is currently exercising its authority under Public Law 85-804 in very limited circumstances, it is my understanding the agency is not providing indemnity until a contract is awarded – and will not guarantee that the indemnity is forth coming as a part of the award process.

IV. USE THE DEFENSE PRODUCTION ACT OF 1950 TO CONVENE A MEETING OF INTERESTED BIDDERS TO CONSIDER COLLABORATION AND ALLOCATION OF PROCUREMENT DOLLARS

The DPA provides the government with authority to permit companies to enter into certain agreements that could include potential competitors and would have the effect of

altering competitive behavior for the development of vaccines and countermeasures – activities which would otherwise violate anti-trust laws. Under the DPA, the government may convene a meeting with or some of the nation's vaccine and countermeasure manufacturers to discuss the government's procurement requirements. If the DPA statutory prescriptions are satisfied, the government's valid exercise of its DPA authority would provide complete protection against the operation of anti-trust laws for the private – entity participants in this process. Given the fifty or more bioterrorist agents identified by the Defense Science Board, it seems reasonable to consider using the Defense Production Act to stimulate and accelerate interest and investment by the new biodefense contractor.

Mr. Chairman, thank you for the opportunity to testify on this tremendously important issue. I will be pleased to respond to any questions from members of the Committee.

I. DISCLOSURE STATEMENT

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4. Pursuant to Rule XI, clause 2(g)(4), of the Rules of the House, please list the amount and source (by agency and program) of each Federal grant (or subgrant thereof) or contract (or subcontract thereof) received during the current fiscal year or either of the two previous fiscal years by you or the entity you represent:

No